

### **REMARKS**

Claims 46-51, 55, 56, 58, 59, 67, and 69-95 have been canceled as non-elected claims, and in consistency with the enclosed Request to Correct Inventorship under 37 CFR 1.48(b), without prejudice for prosecution in a continuing or divisional application. The cancellations are not in acquiescence to any rejection of record.

Claims 52-54, 57, 60-66 and 68 remain pending. Support for the amendments to claims 52 and 54 is found at least on page 5, lines 23-25 of the instant application. Support for the amendments to claim 60 is found at least on page 20, line 30, and page 18, lines 19-26 of the instant application. These amendments, as well as amendments to the other pending claims are supported throughout the instant application, with the amendments to claims 57, and 61-65 directed to correcting minor grammatical inconsistencies of the claims without change in claim scope. The amendments are made for business considerations and to better tailor the claims to encompass commercially contemplated embodiments of the invention at the present time. The amendments are not in acquiescence to any rejection of record.

No new matter has been introduced, and entry of the amendments is respectfully requested.

#### Claim Objections

Claim 51 was objected to as "claiming a nucleic acid of the method of claims 46 or 47." Claims 46, 47, and 51 have been canceled without prejudice for pursuit in a continuing application. Withdrawal of this objection is respectfully requested.

Claims 52-54, 57, and 60-68 were objected to as "depending on or having recited non-elected SEQ ID Nos." Claims 52-54, 57, 60-66 and 68 have been amended to be in relation to SEQ ID Nos 1 and 5 without prejudice and for consistency with the elected invention. Applicants traversal to the Restriction Requirement is maintained for the reasons of record. Claim 67 has been canceled without prejudice for pursuit in a continuing application. Withdrawal of this objection is respectfully requested.

#### Claim Rejections under 35 USC § 112, second paragraph

Claim 67 was rejected under 35 USC § 112, second paragraph for the recitation of “DAM” and “TAA” allegedly “because these terms are laboratory designations and as such are indefinite.” Applicants respectfully traverse at least for the simple reason that if a term is recognized by the skilled person as a “laboratory designation”, then the term is definite to that skilled person for that exact reason. Nevertheless, and in the interest of expediting prosecution rather than in acquiescence to the instant rejection, claim 67 has been canceled without prejudice for pursuit in a continuing application.

Claims 67-68 were rejected under 35 USC § 112, second paragraph for being allegedly “incomplete”. As noted above claim 67 has been canceled without prejudice, and without acquiescence to the instant rejection, for pursuit in a continuing application. Claim 68 has been amended to depend from claim 66. Withdrawal of this rejection is respectfully requested.

Claim 60 and claims dependent therefrom were rejected under 35 USC § 112, second paragraph as allegedly indefinite for reciting “hybridizing”. Applicants respectfully traverse because the term “hybridizing”, while broad, is not indefinite. It is well settled that “breadth is not indefiniteness” (see at least MPEP 2173.04 and the cases cited therein). Moreover, the instant rejection is inconsistent with the rejection of claim 60 under USC § 102 (discussed below) where the meaning of “hybridizing” is sufficiently clear to permit the rejection. Nevertheless, and in the interest of expediting prosecution rather than in acquiescence to the instant rejection, claim 60 has been amended to recite “stringent conditions” as supported by the instant application. Withdrawal of this rejection is respectfully requested.

Claim 52 was rejected under 35 USC § 112, second paragraph as allegedly indefinite for reciting “derivative”. Applicants again respectfully traverse because the term “derivative”, while broad, is not indefinite. As pointed out above, breadth is not indefiniteness, and contrary to the statements in the instant rejection, the term encompasses the results of all methods of “derivatization” as would be understood by the skilled person as well as the examples listed in the statement of the rejection. Applicants thus respectfully submit that no *prima facie* case of indefiniteness has been presented and that this rejection should be withdrawn. Nevertheless, and in the interest of expediting prosecution rather than in

acquiescence to the instant rejection, claims 52 and 54 have been amended to no longer recite “derivative” without prejudice for pursuit of the previous scope of the claims in a continuing application. Withdrawal of this rejection is respectfully requested.

Claim Rejections under 35 USC § 112, first paragraph

Claims 54 and 60-66 were rejected under 35 USC § 112, first paragraph as allegedly “failing to comply with the written description requirement.” Applicants have carefully reviewed the statement of the instant rejection and respectfully traverse because no *prima facie* case of an inadequate written description has been presented.

The instant rejection appears to be based upon the position that because the structure of one variant does not represent the structure of another variant and so the skilled artisan “cannot envision the detailed structure” of the variants “until reduction to practice has occurred”.

Applicants respectfully and strongly traverse because the rejection is based upon incorrect standards for an adequate written description. *A priori*, the standard does not require **actual** “reduction to practice”. It is well settled that U.S. patent law recognizes and permits **constructive reduction to practice** to support patentability.

Moreover, Applicants respectfully submit that there is no requirement for the “envisioning of detailed structures” as asserted in the instant rejection. To the contrary, all that is needed is an adequate description and disclosure of the invention, which in the instant situation, only requires that the skilled person understand and can recognize the meaning of variants and homologues *in the context of the instant invention*. The instant rejection provides no basis for why a skilled person would not have such an understanding.

In light of the above, the instant rejection is misplaced and should not have been made. Nevertheless, and in the interest of expediting prosecution rather than in acquiescence to the instant rejection, the claims have been amended to no longer recite “variant” and “homologue” without prejudice for pursuit of the previous scope of the claims in a continuing application. Withdrawal of this rejection is respectfully requested.

Claims 51-52, 54, and 60-66 were rejected under 35 USC § 112, first paragraph as allegedly “enabling for an isolated nucleic acid that is SEQ ID NO:5 or encodes the ScFv of SEQ ID NO:1 wherein the ScFv binds the 5T4 antigen as well as vectors, isolated plasmids, and isolated host cells and methods of preparing a ScFv”.

Applicants have carefully reviewed the statement of the instant rejection and respectfully traverse because no *prima facie* case of undue experimentation for a broader scope of enablement has been presented.

*A priori*, Applicants respectfully point out that the standard to be applied in establishing a *prima facie* case of non-enablement is set out in part at MPEP 2164.04, including *In re Marzocchi*<sup>1</sup> and the other cases cited therein. With reference to *Marzocchi*, the standard states in part that

“A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the *objective* truth of the statements contained therein which must be relied on for enabling support.” (underlining and italics added)

The above standard requires *objective* reasons to doubt the **presumption** of an enabling disclosure. Thus, there must be *objective* reasons why undue experimentation is necessary to make and use the claimed invention. In the present case, the Examiner has not given *objective* reasons why a skilled person would not be able to make a wide range of variants, homologues, fragments, and derivatives and then identify their ability to bind a 5T4 antigen using only routine and repetitive experimentation that is the antithesis of undue experimentation.

To the contrary, the statement of the rejection asserts many generalities regarding specific situations in the art without demonstration that they apply to the instantly claimed invention. Accordingly, and because no objective reasons based on the claimed invention have

been presented to overcome the **presumption**, no *prima facie* case of non-enablement has been presented and the instant rejection should not have been made.

Nevertheless, and in the interest of expediting prosecution rather than in acquiescence to the instant rejection, the claims have been amended to no longer recite “variant” or “homologue” or “derivative” without prejudice for pursuit of the previous scope of the claims in a continuing application. Additionally, the claims have been amended to recite that the ScFv Ab or fragment thereof “binds to 5T4 antigen”. Applicants respectfully submit that this addresses all concerns raised in the instant rejection as they may apply to the recitation of “fragment” in the claims.

Accordingly, Applicants respectfully request withdrawal of the instant rejection.

#### Claim Rejections under 35 USC § 102

Claims 51, 52, 54 and 60-67 were rejected under 35 USC § 102(b) as allegedly anticipated by Chaudhary et al. Applicants have carefully reviewed the statement of the instant rejection and believe that the rejection is directed to the previous recitation of “variant” in the claims.

In light of the claim amendments and cancellations, Applicants respectfully submit that the instant rejection no longer applies because Chaudhary et al. fail to disclose or suggest the nucleic acids encoding an ScFv antibody (or fragments of such nucleic acids) which *bind 5T4 antigen*. In the absence of such a disclosure or suggestion, Chaudhary et al. cannot anticipate or render obvious the claims, and this rejection may be properly withdrawn.

Claim 60 was rejected under 35 USC § 102(b) as allegedly anticipated by The Promega 1993/94 catalog of nucleic acids (pages 215-216). Applicants have carefully reviewed the statement of the instant rejection and believe that the rejection is based on the belief that primers disclosed in the catalog would hybridize to the previously recited sequences.

In light of the amendment to claim 60, Applicants respectfully submit that the instant rejection no longer applies because the primers in the catalog do not *encode a ScFv that*

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<sup>1</sup> 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

*binds to 5T4 antigen.* In the absence of such a disclosure or suggestion, the catalog cannot anticipate or render obvious the claims, and this rejection may be properly withdrawn.

Claims 51, 52, 54 and 60-67 were rejected under 35 USC § 102(e) as allegedly anticipated by Chester et al. Applicants have carefully reviewed the statement of the instant rejection and believe that the rejection is based on the belief that Chester et al. disclose the materials for, and actual production of, a “ScFv that binds a TAA of CEA”.

In light of the claim amendments and cancellations, Applicants respectfully submit that the instant rejection no longer applies because Chester et al. fail to disclose or suggest the nucleic acids encoding an ScFv antibody (or fragments of such nucleic acids) which *bind 5T4 antigen*. In the absence of such a disclosure or suggestion, Chester et al. cannot anticipate or render obvious the claims, and this rejection may be properly withdrawn.

Claims 51-54 and 60-68 were rejected under 35 USC § 102(a) as allegedly anticipated by Kingsman et al. (WO 98/55607). Applicants have carefully reviewed the statement of the instant rejection and believe that the rejection is based on the difference in inventorship between WO 98/55607 (with Kingsman S.M., Bebbington, Ellard, Carroll, and Myers as named co-inventors) and the instant application (with Kingsman, A., Kingsman, S.M., Bebbington, Carroll, Ellard, and Myers as named co-inventors).

Applicants respectfully refer to the accompanying Request to Correct Inventorship under 37 CFR 1.48(b) which removes co-inventor Kingsman, A. from the instant application in light of the cancellation of claims 46-51, 55, 56, 58, 59, 67, and 69-95 to leave the inventions of claims 52-54, 57, 60-66 and 68 pending. With the deletion of co-inventor Kingsman, A., there is identity between the inventorship named in WO 98/55607 and the inventorship in the instant application. Accordingly, WO 98/55607 is no longer available as a reference under 35 USC § 102(a) and this rejection may be properly withdrawn.

Conclusion

In light of the above amendments and arguments, Applicants respectfully submit that the claims are in condition for allowance and respectfully urge passage of the instant application to issue.

If the Examiner believes a telephonic discussion would expedite prosecution of this application, he is encouraged to telephone the undersigned at the number provided below.

Respectfully submitted,



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